510(K) SUMMARY FOR COLLAGEN SCAFFOLD (CS) – K082079

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Applicant Information

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Device Information

Device Name:	ReGenCollagen Scaffold (CS)
Common Name:	Surgical Mesh
Classification Name:	Surgical Mesh, 21 CFR 878.3300
Classification Code:	FTM
Reviewing Panel:	Orthopedic Devices

Predicate Devices

- Restore Orthobiologic Implant, DePuy Orthopaedics, Inc. (K031969, K001738 and K982330);
- SIS Fistula Plug, Cook Biotech, Inc. (K050337);
- TissueMend, OrthoMend, TEI Biosciences, Inc. (K031188 and K051766);
- Surgisis Mesh, Cook Biotech, Inc. (K974540, K980431, K992159, K034039);
- BioBlanket Surgical Mesh, Kensey Nash, Corp. (K043259 and K041923);
- ZCR Patch, Permacol, Tissue Science Laboratories PLC (K992556, K013625, K021056, K043366, K050355);
- IMMIX Film, OsteoBiologics, Inc. (K024199 and K032673);

- SIS Plastic Surgery Matrix, Cook Biotech, Inc. (K034039)
- Sportmesh, Artimplant (K052830)
- Optimesh, Spineology, Inc. (K014200)
- Marlex Mesh, Davol, Inc. (Pre-amendment).

Device Description

The ReGen Collagen Scaffold (CS) is a resorbable collagen matrix comprised primarily of bovine type I collagen. The CS is provided in a semi-lunar shape with a triangular cross section to be used to reinforce weakened soft tissue and provide a resorbable scaffold that is replaced by the patient's own tissue. The surgeon trims the device to the size necessary for repair of the damaged or weakened soft tissue.

Intended Use

The ReGen Collagen Scaffold (CS) is intended for use in surgical procedures for the reinforcement and repair of soft tissue injuries of the medial meniscus. In repairing and reinforcing medial meniscal defects, the patient must have an intact meniscal rim and anterior and posterior horns for attachment of the mesh. In addition, the surgically prepared site for the CS must extend at least into the red/white zone of the meniscus to provide sufficient vascularization.

The CS reinforces soft tissue and provides a resorbable scaffold that is replaced by the patient's own soft tissue. The CS is not a prosthetic device and is not intended to replace normal body structure.

Substantial Equivalence

The ReGen Biologics Collagen Scaffold (CS) has the same intended use and similar technological characteristics to the predicate surgical mesh devices, including; the DePuy Restore® Orthobiologic Soft Tissue Implant (K982330, K001738, K031969), the Cook Biotech SIS Fistula Plug (K050337), the TEI Biosciences TissueMend and OrthoMend (K031188, K051766), the Cook Biotech Surgisis Mesh, the Kensey Nash BioBlanket™ Surgical Mesh (K043259, K041923), the Tissue Sciences Laboratories' Permacol and ZCR Patch (K992556, K013625, K021056, K043366, K050355), the Organogenesis CuffPatch (K042809), the Cook Biotech SIS Plastic Surgery Matrix (K034039), the Artimplant Sportmesh (K052830) and the Spineology Optimesh (K014200). Any differences identified do not raise new types of safety or effectiveness questions. The questions common to all resorbable surgical meshes have been addressed in this submission by biomechanical, biocompatibility, animal testing, and clinical studies with

the device, including a prospective, randomized multicenter clinical trial that was conducted under an IDE.

This trial had two separately controlled and randomized arms; one arm consisted of 157 patients with no prior surgery to the involved meniscus (Acute) and the other 154 patients with one to three prior treatments to the involved meniscus (Chronic). Patients were followed for a mean of 59 months. Data from this IDE study and a publication in the July issue of the Journal of Bone and Joint Surgery analyzing the data from this multicenter clinical trial were used to support the substantial equivalence of this device. Data from this submission were presented at the November 14, 2008 meeting of the Orthopaedic and Rehabilitation Devices Panel Meeting for the purpose of providing FDA with advice and recommendations.

Based on the data presented, the CS is substantially equivalent to the predicate devices with respect to intended use, material of composition, and technological characteristics.